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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : G09B 23/28 — A1

(11) International Publication Number: WO 94/25948

(43) International Publication Date: 10 November 1994 (10.11.94)

(21) International Application Number: PCT/GB94/00944

(22) International Filing Date: 3 May 1994 (03.05.94)

(30) Priority Data:
9309021.5 30 April 1993 (30.04.93) GB

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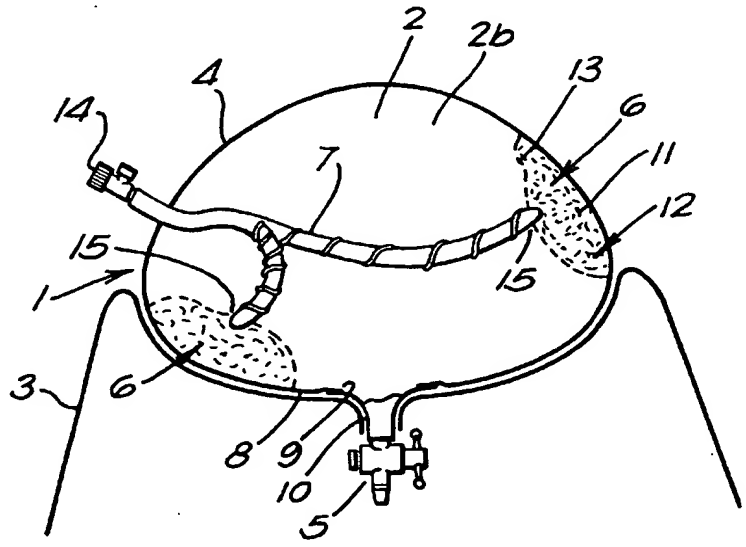
(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), ES, FI, FI (Utility model), GB, GE, HU, JP, KG, KP, KR, KZ, LK, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, SK (Utility model), TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: MEDICAL TRAINING APPARATUS



(57) Abstract

Medical training apparatus comprising a container (1) and liquid (2b) in the container, the container having at least one outer wall (4) of elastomeric material held in tension by the liquid. The apparatus can simulate an abdomen, breast or uterus.

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MEDICAL TRAINING APPARATUS

The present invention relates to medical training apparatus, for example an artificial abdomen, breast or uterus.

Foetal blood sampling (cordocentesis) and other invasive procedures in foetal medicine are now carried out under ultrasound guidance and are finding widespread applications not only for the prenatal diagnosis of inherited disorders but also in the antenatal evaluation of the foetus in high-risk pregnancies and in foetal surgery. As ultrasound technology and training improve, the demand increases for more foetal medicine specialists able to perform those procedures competently. The particular aim of the training is in directing a needle transabdominally towards as target in the foeto-placental unit under complete control and visualisation of both the target and the needle.

Although programmes for training junior doctors in obstetric ultrasound are now well established, the opportunity to acquire the skills to perform cordocentesis is currently available only in a few major foetal medicine centres throughout the world and training is carried out through active supervision of the trainee in the procedure. Unlike training in elective surgical procedures, cordocentesis is performed without sedation as an out-patient procedure. The supervision of the trainee intensifies the anxiety already felt by the patient as a result of the uncertainty over the outcome of the pregnancy. In addition, the complication rate is higher in the initial few procedures or when the procedure is not regularly practised.

Experience shows that invasive procedures must be done by an operator with a free hand technique. A 5cm curvilinear transducer may be used visualising the target in the centre of the screen. The needle must be inserted

3cm from the transducer at a 45° angle with the probe. Some of the most difficult aspects of the procedure are:

Visualising the cord longitudinally at either the umbilical or placental insertion.

Maintaining the transducer in this position throughout the procedure.

Introducing the needle through the skin at the right angle and distance from the transducer.

Advancing the needle under full vision towards and into the cord.

Introducing the needle into the umbilical vein through the "Wharton gelee" surrounding the cord.

Amniocentesis, cordocentesis and chorionic villus sampling require specific and various approaches of the ultrasonographic anatomy of the uterus, the foetus and the placenta.

There is also a need for training junior doctors in the use of ultrasound in the detection and treatment of breast tumours.

According to the present invention there is provided medical training apparatus comprising a container and liquid in the container, the container having at least one outer wall of elastomeric material held in tension by the liquid.

A second aspect of the present invention comprises the use for the purpose of medical training of apparatus comprising a container and liquid in the container, the container having at least one outer wall of elastomeric material held in tension by the liquid.

The container preferably defines a chamber for receiving the liquid. The chamber is preferably sealed, most preferably having sealable valve means for controlling the flow of liquid into and out of the chamber. The liquid may suitably be held in the chamber under pressure so as to hold the elastomeric wall under tension.

The apparatus preferably simulates a portion of the body, for example an abdomen, breast or uterus. Structures simulating biological features may be positioned within the container.

Where the apparatus simulates a pregnant abdomen there may be a simulation of an umbilical cord and at least one placenta in the container, preferably in contact with the liquid. Where the apparatus simulates a breast there may be a simulation of ligaments, fatty tissue and/or a tumour in the container, preferably in contact with the liquid. Where the liquid is held under pressure the pressure may be selected so that the apparatus best simulates the physical characteristics of a breast, uterus or pregnant abdomen.

Structures within the container may contain fake blood to simulate natural blood in, for example, an umbilical cord.

Preferably the elastomeric material surrounds the chamber. Most preferably the container consists of elastomeric material.

A support means may be provided to give shape to the chamber. The support means is preferably rigid and suitably shaped so that the wall of elastomeric material adopts the shape of the outer surface of the portion of the body that is to be simulated by the container. The support means may also simulate the shape of the region of the body adjacent to the portion simulated by the container.

Where material is present to simulate biological features (such as placentas, fatty tissue, ligaments or tumours) this material may suitably be held in place so as to allow the liquid to reach the material. This may suitably be done by means of a second wall secured to the elastomeric material inside the chamber. This wall can hold the simulated biological features in the region between the second wall and the elastomeric material, with there being at least one channel for allowing the liquid to communicate between the chamber and that region. The channel can conveniently be provided as a perforation through the second wall.

Preferably, the container (particularly the elastomeric wall of the container) and the liquid have physical properties and/or responses to ultrasound analogous to body tissue and fluid, and in particular to those of the portion of the body that is to be simulated. In the case where the apparatus simulates a pregnant abdomen the apparatus suitably has properties and/or responses analogous to those of the natural abdomen wall and amniotic fluid respectively. The same also applies to structures positioned within the container.

The present invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a vertical section through a first embodiment of the invention : a simulation of a pregnant abdomen;

Figure 2 is a perspective view of second embodiment of the invention : a second simulation of a pregnant abdomen;

Figure 3 is a vertical section through the apparatus of Figure 2;

Figure 4 is a vertical section through a third embodiment

of the invention : a simulation of a breast.

Figure 1 shows a simulation of a pregnant abdomen comprising an elastomeric container 1 defining a chamber 2 in which water 2b is contained. The container sits in a support 3 which gives a suitable shape to the container - that is it causes the exposed upper elastomeric wall 4 of the container to adopt the shape of a natural pregnant abdomen wall. A valve 5 is provided in the wall of the container to allow the container to be charged with water and to then seal the water, under some pressure, within the container. The pressure of the water holds the elastomeric wall 4 under tension and/or stretches the wall.

The water is a simulation of amniotic fluid and the outer wall 4 is a simulation of a pregnant abdomen wall. Within the container 1 are simulated placentas 6 and a simulated umbilical cord 7.

The materials of which the apparatus is made are chosen so as to simulate not only the physical characteristics of a natural abdomen but also the response of a natural abdomen to ultrasound.

The elastomeric container 1 is formed of pre-vulcanised rubber. This is prepared by a multi-dipping process. To allow the rubber to be removed from its former after dipping, the container is formed of two portions: a main portion 8 having a relatively wide neck 9 through which the former can be removed and a sealing portion 10 which is secured to the main portion 8 after the main portion has been separated from its former. The elastomeric container is at least partially self-sealing to reduce the amount of leakage when needles are inserted in the container during use of the apparatus.

Each simulated placenta 6 is formed of fibrous plastics fragments 11 held in place in a region 12 defined by a

secondary wall 13 secured to the elastomeric container 1. The secondary wall has perforations to allow the water to pass from the chamber 2 into the region 12. The secondary wall is made of pre-vulcanised rubber.

The simulated umbilical cord 7 is suspended in the liquid between the placentas 6. It is made of a pre-vulcanised rubber or elastomeric material with simulated veins charged with fake blood. The cord 7 communicates with a one-way valve 14 for recharging the veins with fake blood. The ends 15 of the umbilical cord are recessed into the placentas 6 to simulate the natural arrangement of these features.

The support is a rigid vacuum-formed plastics member. The shape of the support where it meets the container is configured so that the elastomeric outer wall 4 adopts the shape of a natural pregnant abdomen wall.

The pressure of the liquid in the cavity 2 is chosen so as to best simulate the physical characteristics of a pregnant abdomen. For example, the pressure can be increased to simulate later stages of pregnancy.

To allow the apparatus to accurately simulate the response to ultrasound of a pregnant abdomen the water should be evacuated of air. Distilled evacuated water is preferably used. About 1% by volume of an acrylic copolymer thickener may be added to the water.

Figures 2 and 3 show a simulated abdomen generally similar to that of the first embodiment. In figures 2 and 3 like parts are numbered as for figure 1. In figures 2 and 3 the abdomen comprises a container 1 in two parts: a rigid base 1a and an elastomeric cover portion 1b defining an elastomeric outer wall 4. The cover is held in tension by the water and is held in place by a band 16 tightened by a screw 17.

Figure 4 shows a simulation of a breast comprising an elastomeric container 21 defining a chamber 22 in which water 22b is contained. The container sits in a support 23 which gives a suitable shape to the container. Above the support the container presents an elastomeric outer wall 24. A valve 25 is provided in the wall of the container to allow the container to be charged with water and to then seal the water, under some pressure, within the container. The pressure of the water holds the elastomeric outer wall 24 under tension and/or stretches the wall.

Within the container is a simulated zone of ligaments and fatty tissue 26 and a simulated tumour 27. The container 21 and the support 23 are generally similar to those of the first embodiment. In this embodiment, however, the support is also configured with enlarged upper walls 28 which simulate the area of the chest surrounding the breast. The container 21 is fixed to a web 29 of elastomeric material which is stretched over the support. The web 29 simulates skin and holds the container in place in a recess 30 in the support 23.

The simulated zone of ligaments and fatty tissue 26 is formed of fibrous plastics fragments 31 held in place in a series of regions 32 by a series of secondary walls 33 secured to the elastomeric container 21. The walls 33 have perforations to allow the water to pass into the regions 32. The walls 33 are made of plastics stocking material. As in the other embodiments, the degree of cohesion of the plastics fragments, for example the degree to which they are fragmented or held in bundles can be chosen so as to simulate the response to ultrasound of the biological feature being simulated.

The simulated tumour 27 is made of silicone rubber.

In each embodiment the materials described are by way of example only, and other suitable materials may be

substituted having physical properties and/or responses to ultrasound analogous to those of the natural features to be simulated. For example, the elastomeric outer wall may be made of any suitable elastomeric structure, for example: an outer, epidermis-simulating sheet, made as described in International Patent Application No. PCT/GB93/00088; a sheet of foam latex rubber; a layer of room temperature vulcanisable silicone gel; and a inner layer of hardened, room temperature vulcanisable silicone rubber.

CLAIMS

1. Medical training apparatus comprising a container and liquid in the container, the container having at least one outer wall of elastomeric material held in tension by the liquid.

2. Medical training apparatus as claimed in claim 2, wherein the container includes a valve means for substantially sealing the container.

3. Medical training apparatus as claimed in any preceding claim, wherein the liquid is held in the container under pressure so as to hold the wall of elastomeric material under tension.

4. Medical training apparatus according to any preceding claim, wherein the container is surrounded by elastomeric material.

5. Medical training apparatus as claimed in claims 5, including a support means for supporting at least part of the container so as to cause the wall of elastomeric material to adopt a desired shape.

6. Medical training apparatus as claimed in claim 5, wherein the support means is shaped to simulate the shape of a region of the body.

7. Medical training apparatus as claimed in any preceding claim, having a structure in the container for simulating a biological feature, the structure being in contact with the liquid.

8. Medical training apparatus as claimed in claim 7, wherein the structure is held between the wall of elastomeric material and a second wall, the second wall having at least one perforation therethrough.

9. Medical training apparatus as claimed in any preceding claim, for simulating a pregnant abdomen, breast or uterus.

10. Medical training apparatus as claimed in any preceding claim, wherein the container and the liquid have physical properties analogous to those of body tissue and/or fluid.

11. Medical training apparatus as claimed in any preceding claim, wherein the container and the liquid have responses to ultrasound analogous to those of body tissue and/or fluid.

12. Use for the purpose of medical training of apparatus comprising a container and liquid in the container, the container having at least one outer wall of elastomeric material held in tension by the liquid.

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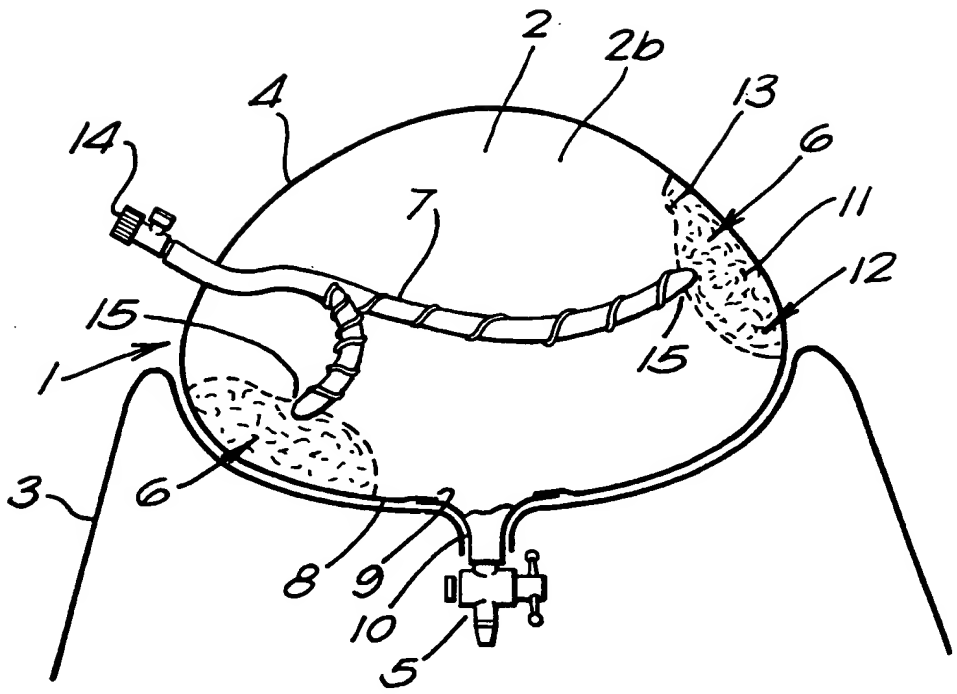
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FIG. 1

FIG. 4

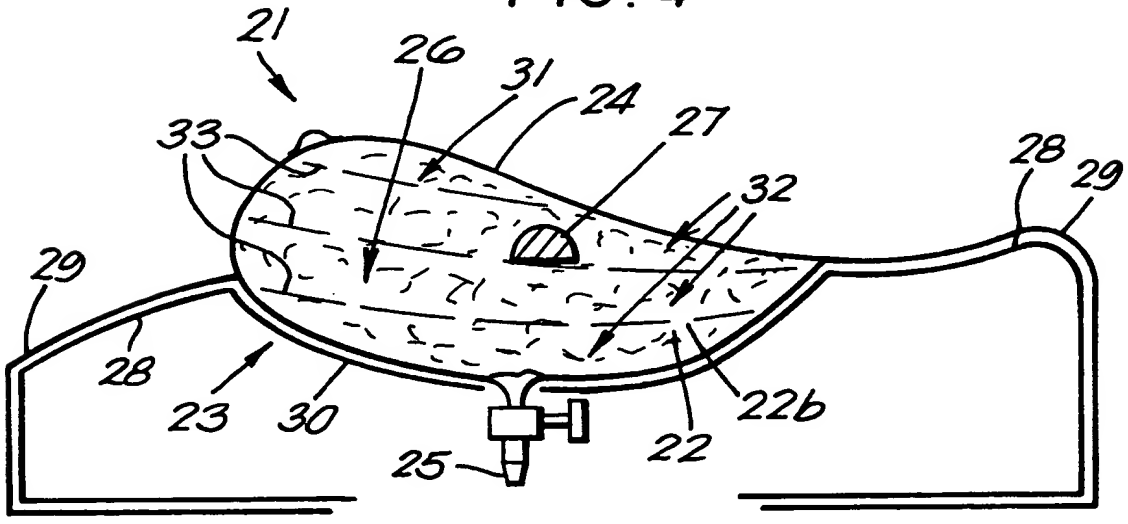
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FIG. 2

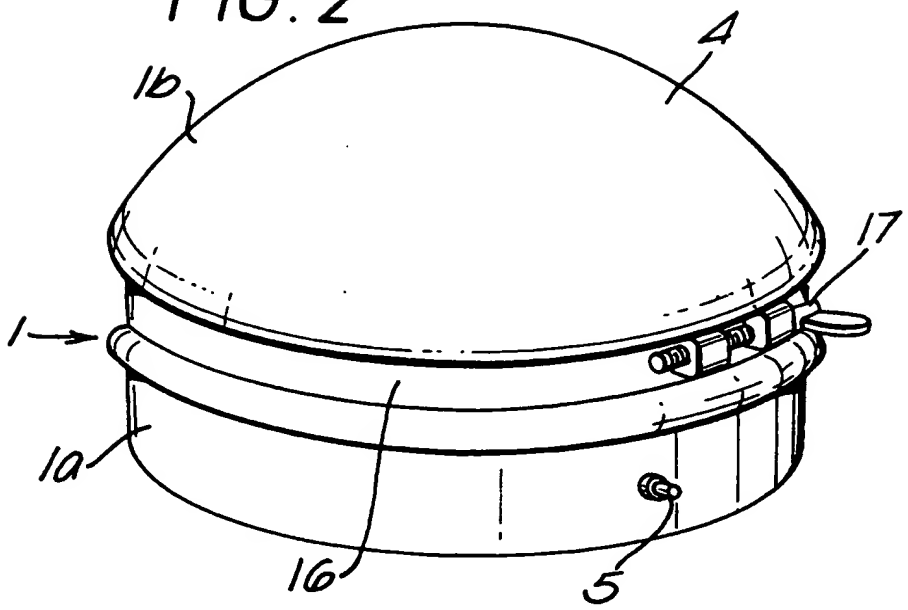
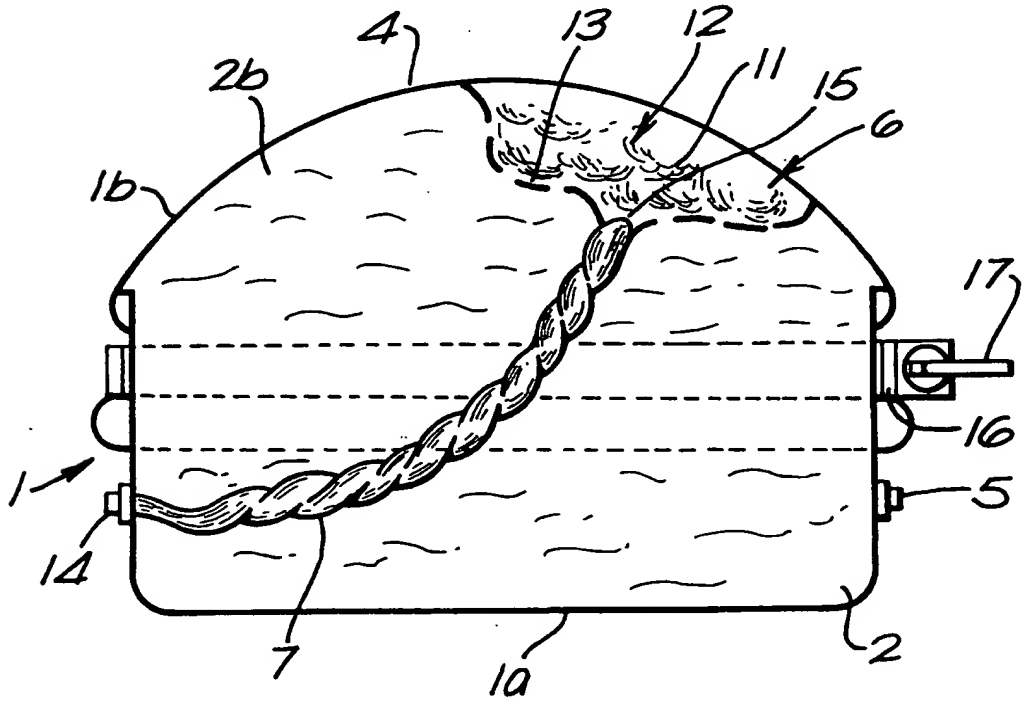


FIG. 3



INTERNATIONAL SEARCH REPORT

Interna ıl Application No
PCT/GB 94/00944

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 G09B23/28

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB,A,2 076 577 (UNIVERSITY OF SURREY; GB) 2 December 1981 see page 1, line 39 - page 1, line 126; claims 1,6-12; figures 1,2 ---	1-4,6,7, 9-12
X	US,A,5 061 187 (JERATH,RAVINDER;US) 29 October 1991 see column 3, line 35 - column 7, line 14; claims 1-9,11-15; figures 1-4 ---	1,3-7, 9-12
X	US,A,4 867 686 (GOLDSTEIN MARK K.; US) 19 September 1989 see column 2, line 46 - column 6, line 63; claims 1-19; figures 1-3 ---	1,4, 7-10,12

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18 August 1994	29. 08. 94

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 055 051 (DUNCAN WILLIAM J.;US) 8 October 1991 see column 5, line 6 - column 8, line 63; claims 1-11,16,24-27; figures 1-6	1,2,4-7, 10-12
A	US,A,4 493 653 (ROBBINS CHESTON W. ET AL.;US) 15 January 1985 see the whole document	1,2,10, 11
A	US,A,4 134 218 (ADAMS,CALVIN K. ET AL.;US) 16 January 1979 see column 4, line 7 - column 6, line 60; figures 1,2	1,4, 7-10,12

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INTERNATIONAL SEARCH REPORT

information on patent family members

Intern al Application No
PCT/GB 94/00944

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US-A-5061187	29-10-91	NONE	
US-A-4867686	19-09-89	NONE	
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